diminishing the effectiveness of the AIDCP.

As a part of the affirmative finding process set forth in 50 CFR 216.24(f)(8), the Assistant Administrator considered documentary evidence submitted by the Government of El Salvador and obtained from the IATTC and determined that El Salvador met the MMPA's requirements to receive a new 5-year affirmative finding.

After consultation with the Department of State, the Assistant Administrator issued a new 5-year affirmative finding to El Salvador, allowing the importation into the United States of yellowfin tuna and products derived from yellowfin tuna harvested in the ETP by purse seine vessels operating under El Salvador's jurisdiction or exported from El Salvador. Issuance of a new 5-year affirmative finding for El Salvador does not affect implementation of an intermediary nation embargo under 50 CFR 216.24(f)(9), which applies to exports from a nation that exports to the United States yellowfin tuna or yellowfin tuna products that was subject to a ban on importation into the United States under section 101(a)(2)(B) of the MMPA, 16 U.S.C. 1371(a)(2)(B).

This new affirmative finding for El Salvador is for the 5-year period of April 1, 2023, through March 31, 2028, subject to subsequent annual reviews by NMFS.

Dated: June 14, 2024.

**Janet Coit,**

*Assistant Administrator for Fisheries, National Marine Fisheries Service.*

[FR Doc. 2024–14330 Filed 6–27–24; 8:45 am]

**BILLING CODE 3510–22–P**

## DEPARTMENT OF COMMERCE

### Patent and Trademark Office

**[Docket No.: PTO–C–2024–0023]**

### Experimental Use Exception Request for Comments

**AGENCY:** United States Patent and Trademark Office, Department of Commerce.

**ACTION:** Notice and request for comments.

**SUMMARY:** The United States Patent and Trademark Office (USPTO), Department of Commerce, is interested in collecting the public's views on the current state of the common law experimental use exception and whether legislative action should be considered to enact a statutory experimental use exception.

**DATES:** Written comments must be received on or before September 26, 2024.

**ADDRESSES:** For reasons of Government efficiency, comments should be submitted through the Federal eRulemaking Portal at *https://www.regulations.gov.* To submit comments via the portal, enter docket number PTO–C–2024–0023 on the homepage and click ''Search.'' The site will provide a search results page listing all documents associated with this docket. Find a reference to this request for information and click on the ''Comment'' icon, complete the required fields, and enter or attach your comments. Attachments to electronic comments will be accepted in Adobe® portable document format or Microsoft Word® format. Because comments will be made available for public inspection, information that the submitter does not desire to make public, such as an address or phone number, should not be included.

Visit the Federal eRulemaking Portal (*www.regulations.gov*) for additional instructions on providing comments via the portal. If electronic submission of comments is not feasible due to a lack of access to a computer and/or the internet, please submit comments by First-Class Mail or Priority Mail to: Christian Hannon, Senior Patent Attorney, Mail Stop OPIA, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450.

**FOR FURTHER INFORMATION CONTACT:** Christian Hannon, Senior Patent Attorney, USPTO, Office of Policy and International Affairs (OPIA), at 571–272–7385.

**SUPPLEMENTARY INFORMATION:** The USPTO is interested in collecting the public's views on the current state of the common law experimental use exception and whether legislative action should be considered to enact a statutory experimental use exception.

#### Historical Development of the Experimental Use Doctrine

The experimental use defense to a claim of patent infringement was first introduced in the landmark case *Whittemore* v. *Cutter.*[1] The *Whittemore* court approved the instruction to the jury that ''the making of a machine fit for use, and with a design to use it for profit, was an infringement'' of a patent right.[2] In assessing this instruction, the court reasoned that ''it could never have been the intention of the legislature to punish a man, who constructed such a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects.'' [3] Thus, the court looked to the prospect of profit-making to determine infringement.[4]

Subsequent courts affirmed *Whittemore's* rationale, finding that experimentation is not a defense to infringement if it creates a benefit for the accused infringer.[5] Thus, in *Bonsack Machine* v. *Underwood,* the court found that experimentation on a patented cigarette machine was not experimental use when the purpose of the experiment was to show superior properties of the defendant's competing product.[6] In *Roche Prod.* v. *Bolar Pharm. Co.,* the court found that ''Bolar's intended 'experimental' use is solely for business reasons and not for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry.'' [7] Notably, the *Roche* court stated that it ''cannot construe the experimental use rule so broadly as to allow a violation of the patent laws in the guise of ''scientific inquiry,'' when that inquiry has definite, cognizable, and not insubstantial commercial purposes.'' [8] Subsequently, in *Embrex* v. *Service Engineering Corp.,* the court denied an experimental use defense because of the district court's determination that the defendant performed tests ''expressly for commercial purposes.'' [9]

The U.S. Court of Appeals for the Federal Circuit revisited the experimental use exception in *Madey* v. *Duke University,* finding that the district court ''erred in applying the experimental use defense.'' [10] The court explained that its precedent does not immunize ''use that is in any way

[1] *Whittemore* v. *Cutter,* 29 F. Cas. 1120 (C.C.D. Mass. 1813) (Case No. 17,600).

[2] Prior to the enactment of the Patent Act of 1952, rights conferred by a patent grant gave a patentee the ''sole and exclusive right and liberty of making, constructing, using, and vending'' his or her invention. Without the written consent of the patent holder, the accused infringing party was required to forfeit and pay damages to the patentee. *See* Patent Act of 1790, Ch. 7, sec. 1, 1 Stat. 109–112 (April 10, 1970).

[3] *Id.; see also Sawin* v. *Guild,* 21 F. Cas. 554, 554 (C.C.D. Mass. 1813 (No. 12,319)) (*stating* that *Whittemore* held that making must be coupled with intent to use for profit).

[4] *Id.*

[5] *Bonsack Mach. Co.* v. *Underwood,* 73 F. 206 (C.C.E.D.N.C. 1896) (*holding* that ''the making of an infringing machine merely as an experiment is not an actionable infringement, but if it is to be used for the purpose of selling the patent under which it is made, it is then to be regarded as use for profit, and a suit will lie for the infringement'').

[6] *Id.*

[7] *See Roche Prod.* v. *Bolar Pharm. Co.,* 733 F.2d 858, 862 (Fed. Cir. 1984) at 863.

[8] *Id.* This holding was effectively superseded by the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly referred to as the Hatch-Waxman Act and codified at 35 U.S.C. 271(e)(1)).

[9] *Embrex, Inc.* v. *Service Engineering Corp.,* 216 F.3d 1343 (Fed. Cir. 2000) at 1349.

[10] *Madey* v. *Duke University,* 307 F.3d 1361 (Fed. Cir. 2002) at 1352.

commercial in nature'' or ''any conduct that is in keeping with the alleged infringer's legitimate business, regardless of commercial implications.'' [11] The court concluded, ''regardless of whether a particular institution or entity is engaged in an endeavor for commercial gain, so long as the act is in furtherance of the alleged infringer's legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense.'' [12] This ''very narrow and strictly limited experimental use defense'' [13] remains the current state of experimental use exception jurisprudence in the United States.

A range of views on the propriety and scope of the experimental use exception arose following *Madey.*[14] Some argued that a narrow exception enhances innovation by rewarding innovators with robust patent rights, while others noted that restricting researcher access to patented technologies would impede innovation.[15]

Previous attempts at codifying the common law experimental use exception have been unsuccessful. For example, section 402 of title IV of the Patent Competitiveness and Technological Innovation Act of 1990 (H.R. 5598) proposed a ''research exemption from patent infringement.'' [16] Additionally, the Genomic Research and Diagnostic Accessibility Act of 2002 (H.R. 3967) proposed amending title 35 of the United States Code to ''provide for noninfringing uses of patents on genetic sequence information for purposes of research and genetic diagnostic testing, and to require public disclosure of such information in certain patent applications.'' [17]

Article 30 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) provides World Trade Organization members the possibility to enact exceptions to patent rights as long as they ''do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interest of the patent owner, taking account of the legitimate interests of third parties.'' [18] The United States has codified a safe harbor provision for certain infringing uses at 35 U.S.C. 271(e)(1). This ''Bolar'' exemption, as it is known, allows for the experimental use of a patented invention by parties to collect regulatory approval data for medical devices or drugs. Other jurisdictions have experimental use exceptions providing broader flexibility.

It should be noted that the Plant Variety Protection Act,[19] which provides Federal intellectual property rights to developers of new plant varieties, contains exemptions that allow for others to use the protected variety in research and for the breeding of new varieties.

**Experimental Use in Other Jurisdictions**

*Europe*

Many European nations, including Germany,[20] the UK,[21] France,[22] Spain,[23] Italy,[24] Switzerland,[25] and the Netherlands [26] have implemented a statutory experimental use exception for otherwise infringing uses. Although the precise application of each of these national exceptions varies based on interpretation in national courts,[27] they are each broader than the U.S. common law exception as they apply to any experimental purpose.

*Asia*

Many countries in Asia have statutory experimental use exceptions. Article 69.1 of Japan's Patent Law provides a statutory experimental use exception.[28] Japanese courts have interpreted this exception to include a Bolar exemption for certain acts related to submissions for regulatory approval.[29] The Japanese Bolar exemption applies to clinical testing not only for generic drugs, but brand-name drugs as well.[30] Similarly, China's Patent Law provides an exception for infringing uses for anyone that ''uses the relevant patent specially for the purpose of scientific research and experimentation.'' [31] Korea's patent law provides that ''[w]orking of [a] patented invention for the purpose of research or experiments'' is not an infringement.[32] Likewise, India's Patent Act provides that a patented invention may be made or used by any person ''for the purpose merely of experiment or research including the imparting of instructions to pupils.'' [33]

*Americas*

Canada and many jurisdictions in Latin America have codified experimental use exceptions. Canadian patent law provides that common law rights, *inter alia,* ''in respect of any use, manufacture, construction or sale of the patented invention solely for the purpose of experiments that relate to the subject-matter of the patent'' are unaffected by the statutory Canadian Bolar exception.[34] Brazil's patent law statutorily exempts ''acts carried out by unauthorized third parties for experimental purposes, in connection with scientific or technological studies or researches'' from patent infringement.[35] Mexico's industrial property law exempts from patent infringement liability ''scientific or technological research activities for purely experimental, testing or teaching purposes.'' [36] Likewise, the industrial property law of the Andean Community [37] grants an exception for ''acts performed for exclusively experimental purposes on the subject

[11] *Id.*

[12] *Id.*

[13] *Id.*

[14] John R. Thomas, *Scientific Research and the Experimental Use Privilege in Patent Law,* CRS Report No. RL32651 (2004). *Available at: https://sgp.fas.org/crs/RL32651.pdf.*

[15] *Id.* at 21.

[16] Patent Competitiveness and Technological Innovation Act of 1990, H.R. 5598, 101st Cong. (1990).

[17] Genomic Research and Diagnostic Accessibility Act of 2002, H.R. 3967, 107th Cong. (2002).

[18] Agreement on Trade Related Aspects of Intellectual Property Rights, art. 30, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 401 [hereinafter TRIPS].

[19] Public Law 91–577, 84 Stat. 1542.

[20] Patentgesetz [Patent Act], Dec. 16, 1980, Bundesgesetzblatt, Teil I, [BGBl I] at 4074, as amended Aug. 30, 2021, section 11 No. 2 (Ger.).

[21] U.K. Patents Act 1977, (1977) art. 60(5)(b), 37 Current Law 1 (Eng.).

[22] French Code of Intellectual Property, L. 613–5.

[23] Law 11/1986 of 20 March on Patents. Art. 52(1)(b).

[24] Industrial Property Code (Legislative Decree No. 30 of February 10, 2005, as amended up to Law No. 102 of July 24, 2023) Art. 68(1)(a) (Italy).

[25] Article 9(e) of the Federal Act on Patents for Inventions, adopted in 2008.

[26] Netherlands Patent Act (15 Dec 1994, as amended) Art. 53(3).

[27] *See* Hans-Rainer Jaenichen and Johann Pitz, *Research Exemption/Experimental Use in the European Union: Patents Do Not Block the Progress of Science,* Cold Spring Harb. Perspect Med. 2015 Feb (explaining that each law has been interested with distinct variations). Available at: *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4315916/#FN4.*

[28] Tokkyoho [Patent L.], Law No. 121 of Apr. 13, 1959 (Japan), amended by Act No. 33 of Jun. 9, 2018 (Japan), art. 69(1) (''A patent right shall not be effective against the working of the patented invention for experimental or research purposes.'').

[29] *Ono Pharma. Co., Ltd.* v. *Kyoto Pharmaceutical Industries, Ltd.,* Saikō-Saibansho [Supreme Court] Apr. 4, 1999, 1998(Ju) 153 (*holding* that clinical trials conducted during the patent term for the regulatory submission of a generic drug should be considered as ''working of a patented invention for testing or research'' as described in Art. 69(1) of the Patent Law and therefore does not constitute patent infringement).

[30] *See X(individual)* v. *Amgen K.K.;* Chiteki-zaisan kōtō-saiban-sho [Intellectual property high court, second division] Feb. 9, 2021, 2020 (Ne)10051.

[31] Patent Law of the People's Republic of China (Dec. 27, 2008), Article 69(4).

[32] Korea Patent Act (as amended Jan. 27, 2010), Art. 96(1).

[33] The Patents Act, 1970, Art. 47(3).

[34] Canadian Patent Act Art. 55.2(6).

[35] Brazil Patent Law No. 9,279 of May 14, 1996; Art. 43(2).

[36] Mexico Industrial Property Law (as amended June 28, 2010), Art. 22(I).

[37] The Andean Community of Nations is made up of Bolivia, Colombia, Ecuador, and Peru.

matter of the patented invention'' and ''acts performed solely for the purposes of teaching or scientific or academic research.'' [38]

**Scope of Interest**

The USPTO is interested in collecting the public's views on the impact of the experimental use exception in all technology areas. For example, one technology area for which greater clarity around the experimental use exception may be of interest is the agricultural industry. In March 2023, the U.S. Department of Agriculture (USDA) issued a report, prepared in consultation with the USPTO, on promoting fair competition and innovation in regards to seeds and other agricultural inputs.[39] In that report, the USDA and the USPTO both committed to evaluating ''new proposals for incentivizing and protecting innovation in the seed and agricultural-related space, including the addition of research or breeders' exemptions for U.S. utility patents.'' [40] This work is consistent with the call in the President's 2021 Executive Order on Promoting Competition in the American Economy. The views submitted in response to this notice will help in conducting this evaluation, as well as evaluating the impact of the experimental use exception in other technology areas.

**Questions for Public Comment**

When responding to the questions, please identify yourself and your interest in the U.S. patent system. If applicable, please indicate whether you fall within one or more of the following categories:

(1) Inventors, patent owners, or investors (*e.g.,* venture capital, investment bank, fund, etc.);

(2) licensees or users of patented technology;

(3) entities that represent inventors or patent owners (*e.g.,* law firms);

(4) recipients of demand letters concerning alleged patent infringement or accused infringers in a patent lawsuit;

(5) entities that represent accused infringers;

(6) government agencies or officials;

(7) academic or research institutions;

(8) intellectual property organizations or associations; and

(9) nonprofit organizations or advocacy groups.

Commenters need not respond to every question and may provide relevant information even if not responsive to a particular question. Unless otherwise specified, the questions are in reference to the U.S. and/or to U.S. laws and regulations. The questions should not be interpreted as an indication that the USPTO has taken a position on or is predisposed to any particular views. The USPTO welcomes comments from the public on any issues that are relevant to this topic, and is particularly interested in answers to the following questions:

1. Please explain how the current state of U.S. experimental use exception jurisprudence impacts investment and/or research and development in any field of technology, including, but not limited to: (a) quantum computing; (b) artificial intelligence; (c) other computer-related inventions; (d) agriculture; (e) life sciences (including prescription drugs and medical devices); and (f) climate-mitigation technologies.

2. Do you believe there are any technologies that are negatively affected by the current state of experimental use exception jurisprudence in the United States? If yes, please identify which technologies and explain how you believe they are affected.

3. Please explain what impact, if any, a statutory experimental use exception would have on the innovation and commercialization of new technologies including with respect to: (a) research and development; (b) ability to obtain funding; (c) investment strategy; (d) licensing of patents and patent applications; (e) product development; (f) sales, including downstream and upstream sales; (g) competition; and (h) patent enforcement and litigation.

4. Has the current state of experimental use exception jurisprudence impacted decisions you have made with respect to filing, purchasing, licensing, selling, or maintaining patent applications and patents in the United States? If yes, please explain how.

5. Please explain whether you believe the United States should adopt a statutory experimental use exception. In doing so, please identify your reasons, including by providing evidence and data to support your views.

6. Please explain how a statutory experimental use exception, if any, should be defined. Please include specific limitations and restrictions you believe would be needed to ensure that patent rights are preserved.

7. Please identify public policy reasons in support of maintaining the status quo or changing the experimental use exception in the United States.

8. Please provide any additional recommendations on how best to enhance and facilitate experimental research on patented inventions in the United States.

**Katherine K. Vidal,**

*Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.*

[FR Doc. 2024–14164 Filed 6–27–24; 8:45 am]

**BILLING CODE 3510–16–P**

[38] Andean Community Decision No. 486 of Sept. 14, 2000, Section 53(b) and (c).

[39] Agric. Mktg. Serv., U.S. Dep't Agric., *More and Better Choices for Farmers: Promoting Fair Competition and Innovation in Seeds and Other Agricultural Inputs,* at 6 (2023).

[40] *Id.* at 6 (2023).

## COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

### Procurement List; Proposed Additions and Deletions

**AGENCY:** Committee for Purchase From People Who Are Blind or Severely Disabled.

**ACTION:** Proposed additions to and deletions from the Procurement List.

**SUMMARY:** The Committee is proposing to add service(s) to the Procurement List that will be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and deletes product(s) previously furnished by such agencies.

**DATES:** Comments must be received on or before: July 28, 2024.

**ADDRESSES:** Committee for Purchase From People Who Are Blind or Severely Disabled, 355 E Street SW, Suite 325, Washington, DC 20024.

**FOR FURTHER INFORMATION CONTACT:** For further information or to submit comments contact: Michael R. Jurkowski, Telephone: (703) 785–6404, or email *CMTEFedReg@AbilityOne.gov.*

**SUPPLEMENTARY INFORMATION:** This notice is published pursuant to 41 U.S.C. 8503(a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

**Additions**

In accordance with 41 CFR 51–5.3(b), the Committee intends to add this services requirement to the Procurement List as a mandatory purchase only for the Little Rock Air Force Base, AR with the proposed qualified nonprofit agency as the authorized source of supply. Prior to adding the service to the Procurement List, the Committee will consider other pertinent information, including information from Government personnel and relevant comments from interested parties regarding the Committee's intent